

EXHIBIT A

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2
3 UNITED STATES COURT OF APPEALS
4 FOR THE TENTH CIRCUIT
5 * * * * *
6 LINDA P. SMITH,
7 Plaintiff-Appellant,
8 -vs- No. 22-4012
9 XAVIER BECERRA, in his capacity
10 as Secretary of the United States
11 Department of Health and Social
12 Services,
13 Defendant-Appellee.
14 * * * * *
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18 TRANSCRIPT OF RECORDED ORAL ARGUMENTS
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21 THE PANEL: CHIEF JUSTICE TIMOTHY TYMKOVICH
22 JUDGE ALLISON EID
23 JUDGE JOEL CARSON
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1 TRANSCRIPT OF ORAL ARGUMENTS, taken in the
2 above-entitled action, from an audio recording of
3 proceedings held on Tuesday, May 17, 2022.
4
5 * * * * *
6 A P P E A R A N C E S
7 JAMES C. PISTORINO,
8 Attorney at Law,
9 appearing on behalf of the
10 plaintiff-appellant;
11 JOSHUA KOPPEL,
12 Attorney at Law,
13 appearing on behalf of the
14 defendant-appellee.
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1 THE CHIEF JUSTICE: I'll call our last
2 case, 22-4012, Smith vs. Becerra. And
3 Mr. Pistorino.
4 MR. PISTORINO: Thank you, Your Honor.
5 James Pistorino on behalf of Mrs. Smith. Nearly
6 five years after submitting -- after presenting
7 her claim for Medicare coverage, Ms. Smith
8 finally reached the district court, the first
9 tribunal in the appeal process with the power to
10 review and invalidate 1682-R. The district
11 court erred as a matter of law when it allowed
12 the Secretary to avoid any judicial review when
13 it concluded that the Secretary's agreement to
14 pay her claims afforded Ms. Smith complete
15 relief and left the court with no power to
16 address the rest of Ms. Smith's causes of
17 action, including her request for injunctive
18 relief against 1682-R.
19 The district court's two-sentence
20 docket entry entering judgment remanding solely
21 for payment of Ms. Smith's claims but failing to
22 make any findings or even consider the
23 nonmonetary relief sought ignores that
24 Ms. Smith's other causes of action were not
25 alternative theories for monetary recovery.

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1 Instead they sought separate nonmonetary relief,
2 including an injunction.
3 JUDGE CARSON: Do you interpret the
4 May 13th revised ruling as basically granting
5 you a successful outcome on all your other
6 pending claims?
7 MR. PISTORINO: When you say the
8 May 13th revised ruling, you mean -- are you
9 referring to the document that was submitted on
10 Friday at 4:15?
11 JUDGE CARSON: Yes.
12 MR. PISTORINO: So the first answer is
13 no. I mean, honestly, again Ms. Smith sought --
14 JUDGE CARSON: You don't interpret
15 that as giving you a win across the board --
16 MR. PISTORINO: No.
17 JUDGE CARSON: -- on pending claims?
18 Why not?
19 MR. PISTORINO: Again first off, again
20 there's no injunction against the enforcement of
21 1682, number one. There's no determination that
22 the Secretary's process of issuing rulings
23 without complying with notice and comment is in
24 violation of the law. Throughout this entire
25 case and throughout the entire really five-year

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1 period this matter has been litigated, the
2 Secretary contends that they have the power to
3 issue rulings in violation of 1395h, the notice
4 and comment provision specific to the Medicare
5 Act, and as the Secretary said below here and
6 somewhat in the papers to this Court, the
7 Secretary contends the district courts have no
8 power to stop the agency from enacting illegally
9 in that way.

10 JUDGE CARSON: So you're not going to
11 declare victory?

12 MR. PISTORINO: No. No, I wish --
13 frankly, I wish I could.

14 JUDGE CARSON: Honestly, we need to
15 determine whether this is still justiciable
16 under the mootness doctrine. What's your kind
17 of best response that it's not moot?

18 MR. PISTORINO: Right. So again
19 obviously we got the same papers you guys got on
20 Friday afternoon. If I could just maybe quickly
21 two -- a few points on that. I actually thought
22 it was quite interesting in that essentially if
23 you were to read that document as sort of across
24 the board, they admitted what I've been saying
25 the entire time, that CGMs are in fact blood

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1 glucose monitors as that term is used in the
2 statutes.

3 JUDGE CARSON: Yeah,
4 congratulations.

5 MR. PISTORINO: Thank you, Your Honor.
6 So across the board admitting, for example, that
7 the technical direction letter you saw mentioned
8 here, that that also did not stop the conduct.
9 Again you saw Judge Mendoza in the Olson case
10 out of Spokane say again that didn't stop it.
11 So through Friday, I'll say in our view, the
12 submission they made admitted that everything
13 they'd said before was wrong and everything we
14 said was right and so the case as it stood
15 before the district court certainly was not moot
16 and you still had the power, now coming to the
17 effect potentially Friday's letter.

18 So generally we would just respond
19 sort of three main points. First, I know we
20 turned in a letter, I apologize for it, late
21 Sunday night citing the W. T. Grant case from
22 the Supreme Court going down the voluntary
23 cessation points and, of course, pointing out
24 that the mere ceasing of the illegal conduct
25 does not deprive the Court of jurisdiction to

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1 issue an injunction is our number one, because,
2 of course, if they just stopped it, it would
3 allow them to continue the illegal conduct on a
4 going forward basis just as soon as this case
5 was resolved.

6 Next we -- let me just make sure I --
7 so I think another important aspect that we
8 could get into, of course, is as we've been
9 saying all along, basically in our view, you
10 just have had faith conduct from the get-go on
11 the 27 -- 1682-R throughout the whole process.
12 So one aspect here is whether or not at the end
13 of the day, and I think as Judge Mendoza said,
14 whether or not they can be trusted with whatever
15 they say now, and I think as Judge Mendoza said,
16 again I know that we cited to, that he had
17 significant concerns that whatever they say
18 could be trusted, and that's one reason there,
19 for example, he said no, it's not moot based on
20 the TDL.

21 JUDGE CARSON: Well, let's just talk
22 about this for just a second, and I don't mean
23 to interrupt. But as far as the claims that you
24 have that are currently ripe for a decision, you
25 win. They agreed to that. You're not worried

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1 that they're going to go back after they
2 confessed error and it was remanded for you to
3 get your damages, that they're going to on those
4 claims try to jerk the rug out from under you
5 and say no, we're not going to pay them, we
6 don't -- we've changed our mind, we're not
7 confessing here, right?

8 MR. PISTORINO: I agree with you in
9 the sense I'm not concerned that Ms. Smith will
10 not be paid for the three claims that are in
11 this case. But I am concerned, number one, that
12 there's been no finding that her CGM is durable
13 medical equipment. Because there's no -- sadly,
14 there's no cure for type 1 diabetes that she
15 suffers from, she will have continued claims
16 going forward. And one aspect --

17 JUDGE CARSON: Right. So let me stop
18 you there, so -- and then you have other claims
19 that are pending that have not been ruled on by
20 a district court.

21 MR. PISTORINO: Correct.

22 JUDGE CARSON: And you also want as
23 part of your relief with respect to your appeal
24 from these three denials, you want relief as to
25 those that you have that are pending?

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1 MR. PISTORINO: No, that's not
 2 correct.
 3 JUDGE CARSON: Well, that's what your
 4 injunction would do, isn't it? If you enjoin
 5 them from enforcing it, then it basically gives
 6 you a win on your other pending claims before
 7 the district court? Because if we're not doing
 8 that, I mean if you win on everything that's
 9 properly up here, what do you have? What are we
 10 enjoining? You've already won.
 11 MR. PISTORINO: So I just want to make
 12 clear because I know there's many different
 13 claims at issue. So we have the three claims at
 14 issue in this case.
 15 JUDGE CARSON: Right.
 16 MR. PISTORINO: Three claims at issue
 17 in this case, let's focus on those for a
 18 moment.
 19 JUDGE CARSON: Right, and that's my
 20 point. I mean there's nobody in this room, is
 21 there, that thinks that those claims are still
 22 in play? You won on those.
 23 MR. PISTORINO: I think with regard to
 24 payment of those three claims, we won. But what
 25 we also asked for again was the nonmonetary

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1 relief, right, and there's different components
 2 of that.
 3 JUDGE CARSON: Okay. But let me ask
 4 you, so your nonmonetary relief as it goes to
 5 those three claims, I mean what is it? I mean
 6 what are you getting with respect to those three
 7 claims other than payment?
 8 MR. PISTORINO: You're getting --
 9 JUDGE CARSON: You submitted them for
 10 payment. They denied it. You appealed. You
 11 won and now -- but you also won an injunction.
 12 I just don't get with those three claims what's
 13 left.
 14 MR. PISTORINO: Right. So you keep on
 15 saying we won, and I agree that we won in terms
 16 of the payment, but again I have multiple causes
 17 of action with different forms of relief. All
 18 the other ones are nonmonetary.
 19 JUDGE CARSON: Okay. So tell me
 20 about -- tell me how the rest of them still live
 21 after you get paid.
 22 MR. PISTORINO: Right. So one thing
 23 we asked for, for example, just the most simple
 24 one, I might say, is a declaration that
 25 Ms. Smith's CGM qualifies as durable medical

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1 equipment under the statute, right. A
 2 declaration of that will have a real world
 3 effect in that in future claims by Ms. Smith,
 4 that would be determined and estop the Secretary
 5 from contending otherwise. We also asked -- we
 6 have a cause of action saying that with regard
 7 to 1682, the Secretary did not comply with
 8 Congress' statute in 1395hh, as signed by the
 9 President, and subjected to notice and comment.
 10 And what we asked for was a
 11 determination that that particular conduct,
 12 issuing rulings without complying with notice
 13 and comment, is violative of the statute, and I
 14 wanted an injunction estopping that. And what
 15 the Secretary has contended all along is, first,
 16 we as the Secretary, I have the power to violate
 17 the laws of Congress, I can act illegally,
 18 that's what they argued below, if you look at
 19 the appendix, their motion for summary judgment.
 20 Assuming I did violate the statute, Court, you
 21 have no power to control me. You cannot stop me
 22 from acting illegally.
 23 So I think that's going to come right
 24 back to your question about what was the effect
 25 of yesterday -- I'm sorry, Friday, what's the

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1 effect of Friday. It just comes back. Have
 2 they ever disclaimed that position? No. That's
 3 the position they maintain. And again coming
 4 back to what they -- or their goal, it appears
 5 to be, is to avoid judicial review of that
 6 solely for the purpose of preserving that claim.
 7 So whatever they did on Friday, right,
 8 again I know what point I have here is that we
 9 keep on calling them rulings, right, 1682-R, the
 10 ruling. It's just a letter written by somebody
 11 at the department, right. The January 17th
 12 letter is just a letter written by a guy,
 13 Patrick McConway (ph.), just a letter written by
 14 a guy, right, totally illegal, again as it's
 15 been found adjudged in the Olson case, bad
 16 faith, just flat-out bad faith. And on the
 17 basis of that, right, again, for five years,
 18 tens of thousands of claims have been denied,
 19 hundreds of thousands actually, and tens of
 20 thousands of people have been injured.
 21 And so if you just look at the conduct
 22 more recently, and candidly, I'm counsel in all
 23 of these cases --
 24 JUDGE CARSON: Right.
 25 MR. PISTORINO: Every single case is

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1 me. Every single step that they have taken has
2 been an effort to avoid judicial review. So
3 when they get a guy, for example, Mr. Olson and
4 then I win, if they could have, they would have
5 paid all his claims to make sure that he never
6 came back while they continued the bad faith
7 conduct, and that's exactly what Judge Mendoza
8 pointed to.

9 JUDGE CARSON: But your theory is that
10 they're going to rescind the rescission and --
11 in other words, they've thrown in the towel
12 through this letter ruling and that your concern
13 is that there is -- as soon as we turn our
14 backs, they're going to rescind that letter
15 ruling and start denying claims again. I mean
16 that's -- is that the path --

17 MR. PISTORINO: So maybe I'll look at
18 it in three ways. First, first, the whole
19 purpose of these efforts by them is to preserve
20 their ability to do exactly that. So your
21 starting point would be -- again just maybe more
22 globally, normally you just look at it and say
23 from the voluntary cessation perspective at just
24 a high level, when someone tells me they're not
25 going to do it, what's the reason I'm going to

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1 trust them, right? Why would I trust them, I
2 think that was a phrase used, whether or not
3 their change of behavior seems genuine, right,
4 and what my point is, across the board here,
5 it's not that it seems genuine.

6 It's the opposite. You know it was
7 bad faith all the way through. That got you to
8 Friday. Now you go to the voluntary cessation
9 principles under which, of course, the Secretary
10 bears -- I think the phrases are typically the
11 formidable burden, the heavy burden, a stringent
12 standard. The Secretary would bear the burden
13 of establishing all of that. And again just
14 coming back, for example, to this Court's case
15 in College America, another case, two main
16 prongs, first the voluntary --

17 JUDGE CARSON: That doesn't sound like
18 something we can do on appeal. That sounds like
19 it needs to be argued somewhere else either in
20 the administrative process or maybe back at the
21 district court.

22 MR. PISTORINO: And at the end of the
23 day, whatever is settled, my point is just it
24 would be the Secretary's burden to establish it
25 and again if you look --

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1 JUDGE CARSON: And he hasn't even
2 tried to do it at this point, right?

3 MR. PISTORINO: Right, right. They
4 haven't tried --

5 JUDGE CARSON: We'll find out in a few
6 minutes, but since Friday they haven't tried
7 to.

8 MR. PISTORINO: They haven't tried to.
9 And again what we would say is again from the
10 voluntary cessation, you can trust me kind of
11 things, what you're looking for are indications,
12 bases under which to credit their statements.
13 So normally it's something formal like a
14 legislature takes action and you know that once
15 the legislature takes action, it's going to be
16 really hard to change that, and that's my whole
17 point here.

18 These "rulings," they're just letters.
19 There's no process. A guy signed a letter in
20 2017. Tens of thousands of people are injured.
21 On Friday, I guess Ms. Brooks decided she --
22 they didn't want to show up here like that. She
23 just signs the letter. If this Court were to
24 dismiss the case, or any court, there's just
25 absolutely no reason the next day, you sign the

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1 letter and it's not like you say, well, I know
2 that won't happen because they're reasonable.
3 No, you know exactly the opposite, right. So --
4 and again the other point, again I just had some
5 notes --

6 JUDGE CARSON: Let me joust with you
7 for a minute about a couple things because what
8 concerns me is there's lots of things up in the
9 air here and a lot of them seem really
10 speculative to me. A lot of the things you say
11 seem to be like concerning what might happen to
12 other people. So I want to make sure we're
13 focused on your client and what you're doing.
14 Because you're not taking the position that you
15 should get an injunction to protect other
16 people, are you? Your position is that you want
17 to go get an injunction so they can't do this to
18 your client going forward, is that right?

19 MR. PISTORINO: I think actually the
20 technical answer would be both.

21 JUDGE CARSON: Okay.

22 MR. PISTORINO: Because again under
23 this, for example, National Mining -- I know I
24 cited cases from this Court, when you're
25 litigating, exactly as we are here, the legality

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1 of the conduct, compliance with the statute,
2 it's not just the statute for in this case
3 Ms. Smith. It's for everybody. So our goal
4 obviously just from a high level --
5 JUDGE CARSON: Right.
6 MR. PISTORINO: -- this case is about
7 \$5,000. No one's going to litigate the case for
8 \$5,000 solely. It's very important to
9 Ms. Smith. There are much bigger principles
10 that are driving it here.
11 JUDGE CARSON: Got it. So I'm just
12 thinking about the district court's remand here.
13 I mean obviously I guess this two-line docket
14 entry was followed up with a judgment.
15 MR. PISTORINO: No, the two-line was
16 the judgment.
17 JUDGE CARSON: It was the judgment?
18 MR. PISTORINO: Yes.
19 JUDGE CARSON: So the court entered
20 judgment --
21 MR. PISTORINO: With the two lines.
22 JUDGE CARSON: -- in favor of you.
23 And so because the government, basically they
24 came in and confessed error?
25 MR. PISTORINO: The court entered --

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1 the Secretary said in so many words --
2 JUDGE CARSON: Right.
3 MR. PISTORINO: -- we'll pay your
4 three claims, we'll give you that money, \$5,000,
5 as long as the court does not address the
6 illegality or any of the other stuff you say,
7 that settlement offer rejected. The court went
8 with that, said, okay, I'm going to adopt the
9 rejected settlement offer. You say he entered
10 judgment for me.
11 He entered judgment saying I want them
12 to pay those three claims and everything else
13 I'm silent on. And I'm sorry, I'm staying over
14 my time.
15 THE CHIEF JUSTICE: We'll continue as
16 long as Judge Carson jousts --
17 JUDGE CARSON: And I won't joust too
18 long, but I'm just -- I mean it concerns me
19 because now what we're talking about is what
20 they might do going forward. And in the face
21 of -- which sounds speculative to me without
22 further denials. It concerns me that maybe this
23 isn't ripe for a decision because the rest of
24 what you want is based on what might happen in
25 the future.

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1 Now, I get what you're saying, look,
2 they're jerking the rug out from under everybody
3 before, they're going to do it again, I don't
4 want to just be right here again arguing the
5 same thing to you and they give us a letter the
6 day before saying they're not going to do it
7 anymore. I get that, but that's sort of what --
8 I'm just struggling with the idea that maybe
9 we're dealing with a case where what you want is
10 an injunction to prevent what might happen in
11 the future, not that, you know, there's any
12 imminent threat that is going to happen.
13 MR. PISTORINO: So if I can -- and
14 again I'm very conscious of my time. And very
15 quickly to try to address it, so first --
16 actually I was just sitting here thinking, at a
17 high level manner, it's so ridiculous, it would
18 be funny except for the tens of thousands of
19 people that have been injured, right, except for
20 the debts, okay, so number one --
21 JUDGE CARSON: Right.
22 MR. PISTORINO: I want to come your
23 point about speculative. I think that's a fair
24 thing, although again I know the second prong of
25 voluntary cessation is complete eradication of

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1 the effect. And of course, because they've been
2 denying these claims for five years, tens of
3 thousands of people have been dissuaded from
4 even submitting the claims.
5 JUDGE CARSON: Right.
6 MR. PISTORINO: So again just from the
7 thing that got submitted at 4:15 on Friday, how
8 would anybody know, right? I mean was there
9 some big publicity campaign that they sent
10 emails -- sent letters to everybody? No. From
11 the public's perspective, it's another secret
12 thing so they wouldn't know. So the second
13 prong they could never show.
14 In terms of speculative, again their
15 whole thing is have they stopped, have they
16 forsworn the claim so they can issue rulings
17 without complying with notice and comment, 1395?
18 No, they have not. They maintain that they
19 still can and that you all are completely
20 powerless no matter how many people they kill.
21 So is it speculative? Not really when that's
22 the power they claim, right. That's what
23 they're claiming as of today.
24 So, you know, again you talk about
25 gamesmanship. Hey, something came in at 4:15,

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1 you know, two business days before their oral
2 argument and the appeal and you just see the
3 efforts of avoiding judicial review, so time and
4 time again. The TDL, that came about because I
5 had a motion for preliminary injunction pending
6 in the Olson case, and I'd already had it
7 pending. They thought they could knock it off
8 with that -- this because I had already argued
9 against the TDL, and it was obviously clearly
10 improper. I appreciate your time. Thank you.
11 THE CHIEF JUSTICE: Are you done?
12 JUDGE CARSON: I'm finished.
13 THE CHIEF JUSTICE: Counsel, you may
14 be seated then. Okay, let's hear from
15 Mr. Koppel for the Department of Human Services.
16 MR. KOPPEL: Good afternoon, Your
17 Honors. May it please the Court, I'm
18 Josh Koppel on behalf of the United States.
19 Plaintiffs sought judicial review of
20 Medicare's denial of three claims for payment.
21 The Secretary confessed error and the district
22 court properly entered judgment for plaintiff,
23 ordering the Secretary to pay the claims.
24 JUDGE CARSON: Okay. So tell me this.
25 What's the effect of that confession? Was it as

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1 represented to me by your opposing counsel was
2 it's these three claims, we'll pay them, but we
3 want nothing to do with any other issue that's
4 on the table?
5 MR. KOPPEL: The effect of the
6 confession in the district court was that these
7 three claims should have been paid and the
8 Secretary will pay them. Now, the Secretary
9 went beyond that and explained that the reason
10 those claims should have covered in the first
11 instance is that plaintiff obtained supplies for
12 an insulin pump that could also perform the
13 functions of a continuous glucose monitor, and
14 insulin pumps have been considered durable
15 medical equipment covered by Medicare since the
16 mid-1990s.
17 The Medicare Appeals Council, they
18 failed to consider that and they got this wrong.
19 So all of Ms. Smith's future claims related to
20 her insulin pump should be paid.
21 JUDGE CARSON: All right. So --
22 MR. KOPPEL: Now even if she didn't --
23 JUDGE CARSON: So is it the
24 government's position that they would be -- I
25 mean through some sort of collateral estoppel or

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1 issue preclusion from denying this claim going
2 forward in the future as to Smith?
3 MR. KOPPEL: I don't know that there
4 would necessarily be collateral estoppel based
5 on that confession of error. That would be, you
6 know, certainly for a future court to decide.
7 But the Secretary has in the meantime taken
8 additional action to ensure that these claims of
9 plaintiff and of third parties will not be
10 denied.
11 The Secretary in November 2020 issued
12 a proposed rule and in December 2021 issued the
13 final rule making clear that adjunctive and
14 therapeutic continuous glucose monitors and
15 insulin pumps that perform the functions of a
16 CGM are durable medical equipment that are to be
17 covered by Medicare. The Secretary -- I'm
18 sorry, the CMS then issued --
19 JUDGE CARSON: Prospectively.
20 MR. KOPPEL: That was prospectively.
21 And then CMS took action to apply that rule
22 retroactively as well, first with the technical
23 direction letter. That was the quickest way CMS
24 could address the issue, although it left gaps,
25 for example, Medicare Part C. And so then CMS

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1 worked toward this ruling that came out last
2 week, and I want to be clear, this is not a
3 letter signed by some guy. This is a ruling
4 signed by the administrator of the Centers for
5 Medicare and Medicaid Services.
6 This is a formal statement of
7 coverage. And so last Friday CMS issued this
8 CMS ruling, formally rescinding the 2017 CMS
9 ruling, and making clear that for pending and
10 future claims, regardless of the date of
11 service, all continuous glucose monitors and
12 insulin pumps that perform the functions of a
13 continuous glucose monitor are durable medical
14 equipment and will be covered by Medicare. That
15 moots this case.
16 JUDGE CARSON: Can that be rescinded
17 tomorrow?
18 MR. KOPPEL: CMS administrative
19 rulings are not that easily rescinded, I'll say
20 that.
21 JUDGE CARSON: They could, though --
22 MR. KOPPEL: In theory, it could be
23 rescinded, but this Court -- and with regards to
24 voluntary cessation, the exception to mootness,
25 we haven't had a chance to really brief this

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1 because the issue just arose. But this Court
2 has repeatedly held that the withdrawal or
3 alteration of administrative policies can moot
4 an attack on those policies and that the mere
5 possibility that an agency might rescind
6 amendments to its actions does not align moot
7 controversy.
8 And I encourage the Court to take a
9 look at Denver Bible Church vs. Polis which was
10 issued this year, Prison Legal News vs. Federal
11 Bureau of Prisons in 2019 and Rio Grande Silvery
12 Minnow vs. Bureau of Reclamation in 2010. All
13 of those cases involved the rescission or
14 alteration of an administrative policy, and this
15 Court held that that rescission or alteration
16 mooted the attack on the policy.
17 The government is accorded a
18 presumption of good faith and unless there is
19 some evidence that the government is going to
20 rescind the rescission, the Court has held that
21 the rescission or alteration moots the claim.
22 JUDGE CARSON: There is a history here
23 of steadfast opposition to their statutory
24 theory. We can't ignore that, can we?
25 MR. KOPPEL: Well, to -- I want to

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1 answer that with -- in two ways. First, I don't
2 think that there is a history of bad faith.
3 Even after some district courts have ruled that
4 continuous glucose monitors are durable medical
5 equipment, CMS did continue to apply the 2017
6 CMS ruling, as it was entitled to do, with
7 regard to other Medicare beneficiaries or other
8 claims.
9 Of course, if there had been a Court
10 of Appeals ruling on that issue, CMS would have
11 had a different policy within that circuit. If
12 there had been a Supreme Court ruling, of course
13 that would have been definitive. But CMS was
14 entitled to continue to apply that ruling and
15 continue to test the ruling in court.
16 In November 2020 CMS reconsidered the
17 issue, you know, in part due to, of course,
18 these repeated holdings by district courts. And
19 the continuous stream of actions since then has
20 been in one direction, so issuing the proposed
21 rule, issuing the final rule, issuing the TDL,
22 issuing this new CMS ruling.
23 Every action CMS has taken has
24 actually been to move toward covering for all
25 dates of service these continuous glucose

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1 monitors as durable medical equipment. So
2 there's no indication that CMS is going to pull
3 the rug out. Second, even aside from mootness,
4 so even if the voluntary cessation exception
5 does apply, there's at least a question -- or at
6 least two questions. First, one of rightness.
7 There's no -- we don't know for sure what CMS
8 will do with any particular claim until CMS has
9 actually done that. And so a judicial ruling on
10 a future claim is not yet right.
11 And second, there's a jurisdictional
12 statutory authority issue, which is that a court
13 doesn't have statutory authority, it doesn't
14 have jurisdiction to consider a Medicare claim
15 until it has been presented to the agency.
16 There's no claim, other than the three here,
17 that have already been paid and judgment has
18 been entered and they've already been paid by
19 CMS. No other claim has yet been presented to
20 the agency and certainly has not yet reached the
21 final agency decision.
22 And so the district court simply
23 doesn't have jurisdiction to consider those
24 future claims.
25 JUDGE CARSON: Aren't all those future

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1 claims going to be paid under the May 13th
2 ruling?
3 MR. KOPPEL: They absolutely should
4 be, and that is just an additional reason that
5 there's no -- there's no cause for the district
6 court to issue a decision on the validity of the
7 2017 CMS ruling. That would be an advisory
8 opinion.
9 And you know, plaintiff has -- shifts
10 tactics here. Instead of simply seeking a
11 decision on the 2017 CMS ruling, which would be
12 an advisory opinion, now plaintiff seeks an
13 advisory opinion on whether CMS rulings
14 generally can be issued without notice and
15 comment. That's certainly an advisory opinion.
16 It depends --
17 JUDGE CARSON: The plaintiff -- are
18 you taking the position that claimants still
19 need to appeal their claims up to the MAC for
20 all these pending cases?
21 MR. KOPPEL: If there is a future
22 claim for coverage of a continuous glucose
23 monitor that is denied, that does need to be
24 appealed to the Medicare Appeals Council. After
25 that, CMS issues a final -- or HHS issues a

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1 final agency decision. Only after that does the
2 statute permit the district court to exercise
3 jurisdiction and provide judicial review.
4 JUDGE CARSON: I guess my question is
5 different then. Are the administrators, the
6 ALJs and the MAC still going to be relying on
7 1682-R --
8 MR. KOPPEL: No.
9 JUDGE CARSON: -- or is that gone?
10 MR. KOPPEL: That is gone. The 1682-R
11 has been rescinded.
12 JUDGE CARSON: So a claim that's
13 pending before the administrator, the ALJ or the
14 MAC basically should be adjudicated immediately
15 in favor of the claimant?
16 MR. KOPPEL: Yes.
17 JUDGE CARSON: Are there any
18 exceptions to that? Will this be all glucose
19 monitoring claimants or do -- I might have heard
20 you say that the monitor needed to be connected
21 to another durable medical device. Did I
22 misunderstand that?
23 MR. KOPPEL: No, the continuous
24 glucose monitor itself is the durable medical
25 equipment. So there are --

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1 JUDGE CARSON: Standing alone, those
2 get covered now under this new policy?
3 MR. KOPPEL: Yes. Of course, provided
4 that the beneficiary actually has diabetes, you
5 know, and that it's diagnosed and they have to
6 be to using a dedicated continuous glucose
7 monitor, not a phone, like an iPhone, because
8 that has a -- the primary purpose of that is not
9 medical. But the mine run of cases, generally
10 speaking, what we're talking about here,
11 continuous glucose monitors starting immediately
12 are considered durable medical equipment. Those
13 claims will be paid. That's regardless of the
14 date service. And even if a claim has been --
15 has already been denied, if that claim is still
16 pending, you know, it's on appeal to an ALJ, the
17 latest CMS ruling issued by the administrator
18 makes clear that that claim is to be reopened
19 and paid.
20 JUDGE CARSON: And I guess this lawyer
21 would know his way around the agency process,
22 but I also have a question on the voluntary
23 cessation. Why doesn't that still need to be
24 resolved somehow, either by this panel or by a
25 district court somewhere? I don't know that

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1 we're in a position to really evaluate that
2 claim yet.
3 MR. KOPPEL: Yeah. So because
4 voluntary cessation goes to mootness and
5 mootness is a jurisdictional issue, I believe
6 that this Court has an independent duty to make
7 a decision on the mootness question itself. You
8 know, some of those cases that I cited, Denver
9 Bible Church, Prison Legal News, Rio Grande, at
10 least some of those I know that rescission and
11 alteration of the administrative policy under
12 attack was issued while the case was on appeal
13 and this Court went ahead and made the decision
14 on mootness itself.
15 And you know, it is true that the
16 court has stated generally the party arguing in
17 favor of mootness bears the burden to show that
18 the challenged action won't be repeated, but the
19 court has also made clear in those cases that
20 where the challenged action was in an
21 administrative policy that has been rescinded or
22 altered, the burden is not quite so burdensome.
23 And in fact, the burden may even shift to the
24 plaintiff in those cases to show that there is
25 some cause to think that the government will

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1 pull the rug out.
2 And certainly, you know, there's no
3 cause to think that these are formal rulings,
4 and keep in mind that the CMS ruling applies to
5 a closed set of cases because for dates of
6 service February 28th, 2022 going forward, those
7 cases, those claims are governed by the 2021
8 final ruling, which went through notice and
9 comment, you know, a very formal rule-making
10 process. That really cannot easily be reversed
11 absent another notice and comment process.
12 So the CMS ruling applies to a closed
13 set of cases that every day is diminishing, and
14 there is no indication that the CMS
15 administrator for any reason would want to all
16 of a sudden switch policy with regard to that
17 closed and diminishing set of cases. And of
18 course, you know, the CMS administrator cannot
19 reverse the 2021 final rule, you know, so
20 easily. So the idea that the CMS ruling will be
21 reversed again as soon as this Court issues its
22 decision is quite implausible.
23 JUDGE CARSON: Let me ask you a
24 question. Are you familiar with the plaintiffs'
25 district court actions that are pending?

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1 MR. KOPPEL: Some of them. I'm not as
 2 familiar with the ones --
 3 JUDGE CARSON: Okay.
 4 MR. KOPPEL: With all of them.
 5 JUDGE CARSON: Do you know as -- why
 6 hasn't the government confessed error in those
 7 cases? Why didn't -- when they determined that
 8 the three claims in this case should be paid
 9 because the interpretation was wrong, why didn't
 10 they confess error in those cases too?
 11 MR. KOPPEL: I'm not -- I'm sorry, I
 12 can't speak to those.
 13 JUDGE CARSON: Okay.
 14 MR. KOPPEL: I'm not familiar enough
 15 with them.
 16 JUDGE CARSON: Let me tell you why I'm
 17 asking you.
 18 MR. KOPPEL: Yeah.
 19 JUDGE CARSON: Because doesn't the
 20 fact that they would confess error here and not
 21 confess error in those cases suggest that it was
 22 gamesmanship to confess error here and get this
 23 case off the books?
 24 MR. KOPPEL: So, you know, one reason
 25 is that the Secretary confessed error here

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1 immediately because plaintiff was using not just
 2 a stand-alone continuous glucose monitor but an
 3 insulin pump that also performs the functions of
 4 a continuous glucose monitor, and that's really
 5 a different category. Insulin pumps have been
 6 durable medical equipment again since the
 7 mid-1990s. So that's why the Secretary was able
 8 to confess error here, you know, so quickly.
 9 I do expect that with this new CMS
 10 ruling, you know, the position may change in
 11 those other courts. I'm not sure --
 12 JUDGE CARSON: I don't understand why
 13 that's different from counsel's other case. As
 14 I understand it, it's the same plaintiff, same
 15 equipment, different payments. These just
 16 happen to have had a decision and could come up
 17 on appeal. Those are still pending with no
 18 ruling. And if they're the same and you confess
 19 as to three and you don't confess as to the
 20 others, I mean doesn't that suggest you're
 21 trying to evade review?
 22 MR. KOPPEL: So it's certainly not the
 23 same plaintiff, I want to be clear about that.
 24 Smith -- this is Smith's only action.
 25 JUDGE CARSON: Okay.

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1 MR. KOPPEL: The other claims are
 2 other plaintiffs. Those other cases also
 3 involve ancillary issues. So, for example,
 4 there's a case in the District of Columbia where
 5 plaintiffs were trying to seek payment of claims
 6 that had not been appealed and where the time to
 7 appeal had run. And so there are questions of
 8 whether the district court had jurisdiction over
 9 those.
 10 I believe that in Olson, some of the
 11 issues relate not to whether the claims should
 12 have been paid but whether -- what the
 13 appropriate relief is, whether injunctive relief
 14 should be issued, attorneys' fees, that kind of
 15 thing. So I don't -- I don't want to speak to
 16 those other cases. I'm not familiar enough with
 17 them to speak to them, but I'm not sure it's
 18 true that the Secretary continues to not pay --
 19 you know, continues to take the position that
 20 continuous glucose monitors are not durable
 21 medical equipment.
 22 JUDGE CARSON: Okay.
 23 MR. KOPPEL: And certainly this latest
 24 CMS ruling I believe should make clear that, you
 25 know, continuous glucose monitors are durable

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1 medical equipment going forward, you know, from
 2 here on, regardless of the date of service, even
 3 for past dates of service.
 4 JUDGE CARSON: Before you sit down, I
 5 had a question on the equitable relief. It
 6 seems to me that the cases that I've reviewed
 7 strongly suggest that 405(g) is a permissible
 8 vehicle for some forms of equitable and
 9 declaratory relief, and I'm not sure you really
 10 denied that or opposed that in your papers. But
 11 do you agree that a district court could order
 12 in an appropriate case some form of equitable
 13 relief, an injunction or a declaratory judgment?
 14 MR. KOPPEL: Califano vs. Yamasaki
 15 holds that some form of equitable relief is
 16 available. I'm not sure -- and we took the
 17 position, although we continue to take the
 18 position that setting aside or enjoining a rule
 19 to apply -- such that the injunction would
 20 require the Secretary to pay future claims that
 21 haven't yet been presented --
 22 JUDGE CARSON: Well, that's a merits
 23 question.
 24 MR. KOPPEL: Right.
 25 JUDGE CARSON: I'm talking about the

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1 broader judicial power question.
2 MR. KOPPEL: There is some set of
3 equitable remedies that are available. You
4 know, Califano vs. Yamasaki addressed equitable
5 powers to ensure the pending -- that the
6 pending -- the status quo remains pending
7 resolution of litigation or to protect the
8 interests of the absent class members. So
9 certainly those kinds of equitable powers are
10 available. You know, here --
11 JUDGE CARSON: I think that's a recent
12 DC circuit case, Parzakansky (ph.), that also
13 suggests equitable relief was proper in some
14 circumstances.
15 MR. KOPPEL: Exactly. But as that
16 case makes clear, and I think that's a very --
17 quite analogous case. Just because Califano
18 held that equitable remedies are available, it
19 doesn't mean -- it didn't determine when they're
20 available. And where the plaintiff, and this is
21 what Parzakansky held, where the plaintiff seeks
22 equitable relief to decide future claims that
23 haven't been yet presented to the agency and
24 haven't yet reached a final agency decision,
25 those equitable remedies are not available.

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1 JUDGE CARSON: But why wouldn't here a
2 declaration that the Secretary's interpretation
3 of the statute is wrong, why wouldn't that --
4 that just seems like a pretty garden variety
5 remedy that, you know, actually to the extent it
6 applies to, you know, thousands of other
7 claimants would be a good thing because it would
8 resolve the legal authority of the agency. You
9 know, maybe the district court issues a
10 declaratory judgment that's appealed to a
11 circuit, you know, or whatever. But that just
12 seems like kind of something that happens every
13 day in the district courts.
14 MR. KOPPEL: So in the appropriate
15 case, a court can rule on the validity of a CMS
16 ruling. So I mean there's a number of reasons
17 that this district court couldn't and shouldn't
18 going forward, you know, mootness, the 2017 CMS
19 ruling has been rescinded, the plaintiff's claim
20 wasn't properly decided under the 2017 CMS
21 ruling because that ruling didn't apply to
22 insulin pumps. The appeals council erred in
23 applying the 2017 CMS ruling to plaintiff's
24 claim.
25 But in a case where, you know, HHS

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1 applies a CMS ruling to a claim properly and the
2 Secretary confess -- you know, contests or
3 continues to contest the claim before the
4 district court, the district court can consider
5 the validity of the CMS ruling and if it's
6 invalid, that would be a basis to reverse and
7 remand.
8 The question that the district court
9 didn't get to, and I don't think this Court
10 needs to, is whether the district court can then
11 issue an injunction saying this CMS ruling also
12 shouldn't be applied in future cases because
13 that decides claims that haven't yet been
14 presented to the agency.
15 But in terms of deciding for purposes
16 of a present live claim for Medicare coverage
17 whether a CMS ruling is properly issued,
18 absolutely the circuit court can do that, and
19 that allows the Court of Appeals to rule on the
20 issue, potentially the Supreme Court, and we
21 certainly don't take issue with that.
22 In this case, however, not only is the
23 issue moot, but for all the reasons we've
24 explained, even if the issue were not moot, the
25 decision of the district court should be

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1 affirmed. Thank you.
2 THE CHIEF JUSTICE: Counsel, we
3 understand both your arguments. Thank you very
4 much for clarifying the situation for us.
5 You're excused. Your case shall be submitted,
6 and the Court will be in recess until 9 o'clock
7 tomorrow morning, I believe.
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1 UNITED STATE COURT OF APPEALS
2 FOR THE TENTH CIRCUIT
3 *****
4 LINDA P. SMITH
5 Plaintiff-Appellant
6 -vs- Case 22-4012
7 XAVIER BECERRA, in his capacity as
8 Secretary of the United States
9 Department of Health and Human Services,
10 Defendant-Appellee.
11 *****
12 CERTIFICATE
13
14 I, LISA A. CREERON, do hereby certify I took in
15 shorthand the proceedings held in the above-entitled
16 matter on the 17th day of May, 2022, and that the
17 attached is a true and correct transcription of the
18 proceedings so taken, to the best of my ability.
19 In witness whereof, I have hereunto set my hand
20 and affixed my seal of office this 21st day of May, 2022.
21
22 Notary Public, State of Wisconsin
23 My Commission Expires: 1/30/2025
24
25

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